

CLAIMS

125
121

1. A controlled release composition for oral administration comprising a) a therapeutically effective amount of levosimendan and b) a drug release controlling component for providing the release of levosimendan over an extended period of time and a steady-state plasma level for metabolite (II) of less than 20 ng/ml, preferably less than 10 ng/ml.

2. A composition of claim 1 wherein the drug release controlling component allows levosimendan to be released substantially completely before the composition reaches the large intestine.

10 3. A composition of claim 1 or 2 wherein the drug release controlling component is hydrophilic gel forming polymer or a vegetable fat or oil or a fatty acid ester.

4. A controlled release composition for oral administration comprising a) a therapeutically effective amount of levosimendan and b) a drug release controlling component for providing the release of levosimendan over an extended period of time, wherein the total in vitro dissolution time, determined according to the USP XXII basket assembly method in phosphate buffer pH 5.8, is substantially between 1 and 4 hours for at least 90 per cent of the content of levosimendan.

15 5. A controlled release composition for oral administration comprising (a) a rapid release portion comprising levosimendan optionally together with at least one excipient, and (b) a controlled release portion comprising levosimendan and a drug release controlling component.

20

6. A composition of claim 5 comprising (a) a rapid release portion in the form of a powder comprising levosimendan together with at least one excipient, and (b) a controlled release portion in the form of granulates comprising levosimendan and a release controlling hydrophilic gel forming polymer.

25

7. A composition of claim 5 or 6 wherein the rapid release portion comprises levosimendan and microcrystalline cellulose.

8. A composition of claim 6 or 7 wherein the release controlling hydrophilic gel forming polymer is hydroxypropylmethyl cellulose, alginic acid or a mixture thereof.

30 9. A composition of any of claims 5 - 8 wherein about 25 - 75 %, preferably about 30 - 70 %, more preferably about 40 - 60 % per weight of the drug is in the controlled release portion.

10. A composition of any of claims 5 - 9 wherein the amount of the hydrophilic gel forming polymer is about 20 - 80 %, preferably about 30 - 70 %, per weight of the composition.

35

2
high oburaw
~ 100
0.58

Add
121